Avoiding Potential Non-Compliances during the transition to the 2015 standard

Presented by Randall D’Amico
August 11, 2015
TÜV SÜD in numbers: Growing from strength to strength

<table>
<thead>
<tr>
<th>1</th>
<th>One-stop technical solution provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>150</td>
<td>years of experience</td>
</tr>
<tr>
<td>800</td>
<td>locations worldwide</td>
</tr>
<tr>
<td>2,060</td>
<td>million Euro in sales revenue 2014</td>
</tr>
<tr>
<td>22,000</td>
<td>employees worldwide</td>
</tr>
</tbody>
</table>

Note: Figures have been rounded off.
Global expertise. Local experience.

Legend:
- Countries with TÜV SÜD offices
- Regional headquarters

Note: Figures have been rounded off.

<table>
<thead>
<tr>
<th>GERMANY</th>
<th>INTERNATIONAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Euro 1,240 mio</td>
<td>Euro 820 mio</td>
</tr>
<tr>
<td>10,400 staff</td>
<td>10,800 staff</td>
</tr>
</tbody>
</table>
TÜV SÜD America Inc.

- TÜV SÜD America Inc., founded in 1987, is the North American subsidiary of TÜV SÜD AG.

- TÜV SÜD America Inc. provides complete services through its divisions:
  - Product Service
  - Management Service
  - Industry Service
  - Chemical, Oil & Gas
  - Global Risk Consultants (GRC)
  - RCI Consultants
THE NUMBERS BEHIND ACCREDITED CERTIFICATION USAGE AND VALUE

TIMING
71% found process met expectations with only 7% feeling the process too long.

ACCREDITATION
Nearly every business considers it highly important that their certification is covered by accreditation.

<table>
<thead>
<tr>
<th>Importance Level</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not important</td>
<td>3%</td>
</tr>
<tr>
<td>Average</td>
<td>10%</td>
</tr>
<tr>
<td>Fairly important</td>
<td>33%</td>
</tr>
<tr>
<td>Very important</td>
<td>40%</td>
</tr>
<tr>
<td>Essential</td>
<td>40%</td>
</tr>
</tbody>
</table>

COMPLEXITY
Nearly an even split between an average or complex process.

<table>
<thead>
<tr>
<th>Complexity Level</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very simple</td>
<td>41%</td>
</tr>
<tr>
<td>Fairly simple</td>
<td>41%</td>
</tr>
<tr>
<td>Average</td>
<td>7%</td>
</tr>
<tr>
<td>Fairly complex</td>
<td>8%</td>
</tr>
<tr>
<td>Highly complex</td>
<td>8%</td>
</tr>
</tbody>
</table>

VALUE
62% of responders agree or strongly agree the certification process provided value for the money.

DRIVER FOR SEEKING CERTIFICATION
Internal and external desire to improve quality

47% of respondents stated the primary driver was to improve internal business operations and processes. 32% reported their customers required it, while 13% stated it was to satisfy regulatory requirements. Other reasons cited included using it as a marketing tool or to achieve a competitive advantage.

BENEFITS OF CERTIFICATION
Sales up, regulatory requirements met, and customers pleased

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>VALUE</td>
<td>84%</td>
</tr>
<tr>
<td>SALES</td>
<td>51%</td>
</tr>
<tr>
<td>REQUIREMENTS</td>
<td>80%</td>
</tr>
<tr>
<td>CUSTOMERS</td>
<td>81%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
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<tr>
<td>CUSTOMERS</td>
<td>81%</td>
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</tbody>
</table>

TÜV SÜD
### Accredited Registration Programs (Standards)

<table>
<thead>
<tr>
<th><strong>Quality</strong></th>
<th><strong>Other Systems</strong></th>
<th><strong>Safety / Security</strong></th>
<th><strong>Food</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 9001</td>
<td>R&amp;TTE Directive</td>
<td>OHSAS 18001</td>
<td>ISO 22000</td>
</tr>
<tr>
<td>ISO / TS 16949</td>
<td>Annex V (FQA)</td>
<td>BS 8800</td>
<td>FSSC 22000</td>
</tr>
<tr>
<td>TL 9000</td>
<td>PQC</td>
<td>ISO 27001</td>
<td>SQF 1000 &amp; 2000</td>
</tr>
<tr>
<td>AS9100</td>
<td>Supplier Audits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS9120</td>
<td>Risk Management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ESD 20.20</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>ISO 20000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Environmental</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>ISO 14001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISO 50001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QC 080000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Responsible</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recycling (R2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Social compliance</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SA8000/260000</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

TUV SUD has issued over 43,000 Certificates
Agenda

- Revision Timeline
- Major Changes in 2015
- How to Avoid Non-compliances
- Recommendations
- Conclusion
Agenda

- Revision Timeline
- Major Changes in 2015
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Major Changes

Based on Final Draft of ISO9001:2015

- Changed from eight elements to ten
- Relaxed requirements for documentation
- Changed methodology to define scope of QMS – Removed emphasis on formal documentation of exclusions in Quality Manual
- No requirement for a designated management representative
- Shift from management responsibility to leadership
- Focus on stakeholder relationship management
- Must understand context of the organization
- Risk thinking based approach
- Improves alignment with other standards
## Major Changes

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1. Scope</td>
<td>1. Scope</td>
</tr>
<tr>
<td>2. Normative references</td>
<td>2. Normative references</td>
</tr>
<tr>
<td>3. Terms and definitions</td>
<td>3. Terms and definitions</td>
</tr>
<tr>
<td>4. Quality management system</td>
<td>4. Context of the organization</td>
</tr>
<tr>
<td>5. Management responsibility</td>
<td>5. Leadership</td>
</tr>
<tr>
<td>7. Product realization</td>
<td>7. Support</td>
</tr>
<tr>
<td>8. Measurement, analysis and improvement</td>
<td>8. Operation</td>
</tr>
<tr>
<td></td>
<td>9. Performance evaluation</td>
</tr>
<tr>
<td></td>
<td>10. Improvement</td>
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## Major Changes

### Difference in terminology

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Products</td>
<td>Products and services</td>
</tr>
<tr>
<td>Exclusions</td>
<td>Not used, applicability</td>
</tr>
<tr>
<td>Documents, records</td>
<td>Documented information</td>
</tr>
<tr>
<td>Work environment</td>
<td>Environment for the operations of processes</td>
</tr>
<tr>
<td>Purchased product</td>
<td>Externally provided products and services</td>
</tr>
<tr>
<td>Supplier</td>
<td>External provider</td>
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</table>
### Documentation requirements have been reduced

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>Quality Manual</td>
<td>Quality Policy</td>
</tr>
<tr>
<td>Quality Policy</td>
<td>Scope</td>
</tr>
<tr>
<td>Document Control</td>
<td>Quality Objectives</td>
</tr>
<tr>
<td>Control of Records</td>
<td>Maintain documents necessary</td>
</tr>
<tr>
<td>Control of Non-conforming material</td>
<td></td>
</tr>
<tr>
<td>Corrective Action</td>
<td></td>
</tr>
<tr>
<td>Preventive Action</td>
<td></td>
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</table>
Major Changes

Maintain documented information

- Replaces document, or documented procedure
- Does not exclude the possibility the organization may need to retain that same information for a particular purpose

Retain documented information

- Replaces records
- Organization is responsible for determining what information needs to be retained, and for how long, and in what media
### Major Changes

**Removed exclusions**

|---------------|---------------|
| • Could take exclusion to certain clauses in element 7, i.e.  
  – Design  
  – Service | • Can take exclusion to any part of standard |
| • Had to provide justification | • Justification must be provided |
| | • “If any requirement(s) of this International Standard cannot be applied, this shall not affect the organization's ability or responsibility to ensure conformity of products and services. The scope shall be available and maintained as documented information stating the:  
  – Products and services covered by the quality management system  
  – Justification for any instance where a requirement of this international standard cannot be applied” |
Major Changes

Leadership

- Removed requirement for a designated management representative
- Top management now responsible for all the activities formerly assigned to management rep
  - Taking accountability of effectiveness of QMS
  - Promoting awareness of process approach
  - Retain ultimate responsibility for implementation consistent with the requirements of the standard.
- Added requirement for “engaging”
Major Changes

Context of the organization

- Two clauses relating to the context of the organization
- 4.1 Understanding the organization and its context
  - Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social, and economic environments
  - Internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization
- 4.2 Understanding the needs and expectations of interested parties
  - The organization shall determine a) the interested parties that are relevant to the QMS and b) the requirements of these interested parties that are relevant to the QMS
Major Changes

Risk Based Approach

- Does not require the application of a standardized risk management approach i.e. FMEA, PFMEA
- Does not contain requirement for Preventive action
- “Actions taken to address risk and opportunity shall be proportionate to the potential impact of the conformity of products and services” FDIS ISO 9001:2015
Agenda

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How to Avoid Non-Compliances

Process Approach

- Strengthens the importance of applying a process approach in developing, implementing and improving the effectiveness of an organization’s quality management system.
- Required to define inputs and expected outputs of each process, and to identify key performance indicators.
How to Avoid Non-Compliances

Documentation (7.5)

- Revised documentation requirements are likely to introduce a different kind of recordkeeping burden
- Greater flexibility in the types of documentation that are permitted
- Need to provide evidence of a robust recordkeeping system that provides a thorough history of all quality management activities.
How to Avoid Non-Compliances

Retain Documented Information (7.5.3)

• The organization shall retain documented information on the release of products and services. The documented information shall include:
  • Evidence of conformity with the acceptance criteria
  • Traceability to the person(s) authorizing the release
  • FDIS ISO9001:2015
How to Avoid Non-Compliances

Risk Analysis (6.1)

- No formal requirement for approach
- Suitable for the organization
- Consider the risk/opportunity before deciding how to proceed
- Manage risk like any other decision
- The bigger the risk, the more formal process should be
How to Avoid Non-Compliances

• **Definition of Risk:**
  - A *probability* or *threat* of *damage, injury, liability, loss*, or any other negative occurrence that is caused by external or internal *vulnerabilities*, and that may be avoided through pre-emptive *action*.

• **Risk Management:**
  - The identification, *analysis, assessment, control*, and *avoidance*, minimization, or elimination of unacceptable *risks*.

Source: http://www.businessdictionary.com/definition/risk-management.html
How to Avoid Non-Compliances

Leadership (5.1)

• The requirement for increased leadership oversight for an organization’s quality management system could be the biggest challenge.
• Meeting the threshold of this requirement involves the full engagement of top management.
• Must understand the role that a commitment to quality plays in achieving organizational goals.
• Provide training on effective quality management.
How to Avoid Non-Compliances

Context (4.1)

- Understanding external and internal issues that are relevant to its purpose and strategic direction
  - External can include legal, technological, competitive, economic or other issues, being foreign or domestic
  - Internal can include values or culture that affect ability to achieve intended results
  - Can include positive and negative factors
How to Avoid Non-Compliances

Justification for non applicability (4.3)

- Be wary of excluding things you need or do
- Justification must be provided, explaining why it doesn’t have any effect on your quality system
- Not a free for all where you can stop doing things you don’t like
Quality Objectives

• Shall establish quality objectives at relevant functions, levels and processes
• Be monitored, communicated and updated as appropriate
• Must maintain documented information
How to Avoid Non-Compliances

Organization shall determine

• What will be done
• What resources will be required
• Who will be responsible
• When it will be completed
• How the results will be evaluated
How to Avoid Non-Compliances

Root Cause

• Increased emphasis on process requires a significant effort to identify and investigate root cause issues that impact performance and require corrective actions.

• Most organizations are not sufficiently trained in root cause analysis, and may struggle to develop and implement processes that uncover the underlying basis for nonconformities that are identified.
Interested parties (4.2)

- Organization must communicate with interested parties.
- Can extend beyond customers to include employees, suppliers, partners and even regulatory authorities.
- No requirement to consider interested parties if the organization decides those parties are not relevant to its QMS.
How to Avoid Non-Compliances

Externally Provided Processes (8.4)

• Lumps everything into one group, be it purchased from a supplier, a service provided or a process outsourced to an external provider
• Must strengthen relationship with providers of outside processes or toll good providers
• Controls can vary depending on the nature of the provided process or service
• Use risk based thinking to determine type and extent of controls
How to Avoid Non-Compliances

**Work Environment (7.1.4)**

- Organization shall determine, provide, and maintain the environment necessary for the operation of its processes
- Can include
  - Social - non discriminatory, calm, non-confrontational
  - Psychological – stress reducing, burn out prevention
  - Physical - temperature, heat, humidity, light, airflow
- Difficult to audit
- Open to interpretation
- Risk based thinking
<table>
<thead>
<tr>
<th></th>
<th>N/C Corrected</th>
<th>C/A Plan Accepted</th>
<th>C/A Implemented</th>
<th>C/A Effective</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>X</td>
<td>X</td>
<td>OK</td>
<td>OK</td>
</tr>
</tbody>
</table>

**Revision Timeline**

**Major Changes in 2015**

**How to Avoid Non-compliances**

**Recommendations**

**Conclusion**
Recommendations

Conduct a gap analysis

• Identifying the gaps between current practices and the new requirements is the most effective way to evaluate the changes that are required in your current quality management system.
Develop an implementation plan and timetable

- A formal implementation plan and schedule will help your organization address the required changes within the anticipated three year transition period.
Provide appropriate training for all parties

- Ongoing education and training for all relevant personnel is critical to achieving the goals of your transition plan. More important, educated stakeholders are vital in ensuring ongoing compliance once the transition is completed. A formal implementation plan and schedule will help your organization address the required changes within the anticipated three year transition period.
Recommendations

**Update existing quality management system documentation**

- As noted above, clear and thorough documentation is essential to demonstrate compliance with the requirements of the revised standard and to help reduce the risk of nonconformities
Involve your certification partner early in the process

An experienced certification body can provide invaluable assistance in the process of transitioning to the requirements of ISO 9001:2015. Their early involvement can help your organization save time and money.
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Conclusion

- Complete revision
  - Pulls in elements of other standards
- No need to change numbering of your documents
  - Could create a cross reference table
- Must incorporate risk analysis for decisions
  - Determine program
  - Be consistent with application
  - Document decisions
- Better control of externally provided products, processes and services
- Reduced documentation requirements
- Increased focus on leadership
Conclusion

- Greater emphasis on retaining documented information instead of prescribed quality records
Recommendations

• Gap analysis
  – Perform a self evaluation to see where your weaknesses are

• Implementation schedule
  – A slow, deliberate process better than fire drill

• Training
  – Send one or more people to a training session so they can champion the conversion

• Update documentation
  – While no formal documented procedures are required, documentation requirements exist, so not a bad idea to keep what you’ve got and revise to include 2015 requirements
• TÜV SUD has a resource page on our website that has info on ISO 9001:2015, as well as an “Ask the Expert” button, where you can submit any additional questions you may have.

Questions?
Contact us today

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THANK YOU